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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,864	10/20/2005	Lorenzo Francesconi	GBR-PT006	9662
3624 VOLPE AND F	7590 09/18/200 <b>KOENIG, P.C</b> .	EXAMINER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/533,864	FRANCESCONI, LORENZO			
Office Action Summary	Examiner	Art Unit			
	Monique R. Jackson	1794			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1) Responsive to communication(s) filed on					
	-· action is non-final.				
<i>,</i> —	, <del>-</del>				
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
		3 G. <b>3</b> . <b>2</b> . 6.			
Disposition of Claims					
<ul> <li>4)  Claim(s) 1-17 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1-17 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>					
Application Papers					
9)⊠ The specification is objected to by the Examiner.					
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5/5/05, 6/30/05.	4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal Pa 6)  Other:	te			

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## **DETAILED ACTION**

## **Specification**

1. The disclosure is objected to because of the following informalities: section headings are needed, particularly "Brief Description of the Several Views of the Drawing(s)".

Appropriate correction is required.

## Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For the following reasons, the claims are indefinite:
  - a. The use of the term "it" in Claims 1-2, 9-14 and 16 render the claims indefinite because there is no clear antecedent basis for the term "it".
  - b. In Claims 1 and 2 the terms "high content of exclusively polymer plasticizers of the PPA type and the like" (lines 3-4); and "thin outer layer[s] of non-toxic thermoplastic synthetic resin capable of preventing the transmission of particles present in the PVC" in lines 4-6 render the claims indefinite. The terms "high content" and "thin outer layer[s]" are relative terms which render the claims indefinite given that the terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear how much of the polymer plasticizer needs to be incorporated in order to be considered "high content", 10wt%, 20wt%, 30wt%, more than

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50wt%, 80wt%; or how thick or how thin the outer layers need to be in order to be considered "thin". With regards to the term "PPA type", it is noted that the first occurrence of the abbreviation PPA in the claims should be accompanied by the full term to clarify what the abbreviation stands for; further, it has been held that the use of the term "type" extends the scope of the expression as to render it indefinite. See *Ex parte Copenhaver* 109 USPQ 118. Additionally, it is noted that the claims do not previously recite the incorporation of any particles; hence it is difficult for one having ordinary skill in the art to determine whether the synthetic resin outer layers are "capable" of preventing transmission of particles that have never been defined. What type of particles, how big are the particles, are they on the order of millimeters, microns, nanometers? The size and type of the particle would directly affect their transmission properties.

- c. Regarding claim 3, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

  See MPEP § 2173.05(d). In addition, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).
- d. Claim 4 recites the limitation "thickness of the order of 8tm to 20, um and the thin outer layers have thicknesses from 2, um to 5 p, m" in lines 2-3, however the ranges are unclear and it is further noted that Claim 1 only recites one outer layer not layers.
- e. Claim 5 recites the limitation "the polymer plasticizer in the intermediate layer of PVC" in line 2. There is insufficient antecedent basis for this limitation in the claim

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given that there is no previous recitation to an intermediate layer and Claim 1 only recites a two layer structure. Also, the "by weight" limitation should not be in parenthesis given that parenthetic expressions in the claims are unclear as to whether they are meant to be part of the claim are not.

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- f. Claim 6 recites the limitation "the polymer plasticizer present in the principal thickness" in line 2. There is insufficient antecedent basis for this limitation in the claim given that there is no previous recitation to a principal thickness nor any indication in the parent claims that any of the layers are considered the "principal" layer. The claim further recites "one or more of the group comprising polyesters of sebacic acid..." however the term "the group comprising" is not proper Markush claim format and actually extends the "group" to include elements of the group that have not been clearly defined. Therefore, the limitation is open-ended given the "comprising" and any polymer plasticizer, taken in its broadest sense, can be included.
- g. Claim 7 recites the limitation "is selected from the plasticizers HEXAPLAS and SANTICIZER 438 or mixtures of these and/or PRIPLAST 3149, and others" in lines 2-4; however it is noted that the use of these trademarks in the claim renders the claim indefinite given that the composition of these trademarked products may change over time. Further, the proprietary nature of trademarks utilized in a patent application should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks, wherein it is noted that the use of trademarks in a claim might adversely affect their validity as trademarks. In addition, the term "and others" renders the claim(s) indefinite because the claim(s) include(s) elements

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not actually disclosed (those encompassed by "and others"), thereby rendering the scope of the claim(s) unascertainable.

- h. Claim 8 recites the limitation "vinyl acetate content of less than 10%" but does not recite the basis for this percentage, weight %, molar %, etc.
- i. Claim 9 recites the limitation "Film according to Claim 1, characterized in that it comprises EVA-PVC-EVA"; however, it is unclear what the "EVA-PVC-EVA" is intended to encompass (A copolymer? A blend? A layer structure?), particularly since Claim 1 refers to a two layer structure and not a three layer structure. Also, the Examiner notes that the art accepted manner of describing the layers of a multilayer structure is the use of the slash "/" not the dash "-" mark, e.g. EVA/PVC/EVA. Similarly, Claims 10-14 are also unclear.
- j. Claim 15 recites a parenthetic expression which renders the claim indefinite because it is unclear whether the limitation within the parenthesis are meant to be part of the claim or are just example substances not part of the claimed invention.
- k. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.
- 1. It is also noted that the transitional phrase "characterized in that" does not conform to current accepted U.S. practice; and Claims 3-16" should probably recite "The film" as opposed to just "Film".

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## Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 4. Claims 1-5, 7-9, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimo et al (USPN 4,855,181.) Shimo et al teach a laminate comprising a base material comprising a plasticized polyvinyl chloride resin and a blend layer on one or both surfaces thereof, comprising a blend of polyesteramide and ethylene-vinyl acetate copolymer, namely EVOH as a saponified EVA (reads upon "non-toxic thermoplastic"; wherein the base material layer and the EVOH layer adhere firmly to each other, and the structure exhibits excellent gas barrier properties, prevention of plasticizer bleeding and soil prevention (Abstract; Col. 4, lines 19-21.) Shimo et al teach that most polyvinyl chlorides contain plasticizers in a content of usually 25 to 55% by weight relative to the total weight, and that suitable plasticizers include plasticizers that are solid at room temperature including phthalate-related plasticizers such as phthalic acid diesters having not less than 13 carbon atoms in the alcohol component thereof, and aliphatic esters of dipentaerithritol (Col. 4, line 47-Col. 5, line 14; wherein the Examiner takes the position that the solid plasticizers recited above read upon the claimed "and the like" as well

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as claimed "and others".) Shimo et al teach that the ethylene content of the EVA copolymer is preferably 55mol% or less, preferably 50 mol% or below; with a saponification degree of preferably 95% or more (hence a vinyl acetate content of less than 5% as claimed; Col. 5, lines 11-30.) Shimo et al teach that the thickness of the blend layer(s) is about 0.05 to about 20  $\mu$  and that the laminate can be formed by coextrusion to produce films, sheets or tubes (Col. 4, lines 33-56.)

5. Claims 1-5, 7-9, 12, and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Wofford et al (USPN 6,214,477.) Wofford et al teach a multilayer film comprising a first layer including polyvinyl chloride; and a second layer including a material such as anhydride functionalized polyolefin, ethylene/vinyl acetate copolymer having a vinyl acetate content of between 10% and 35%, ethylene/alkyl acrylate copolymer having an alkyl acrylate content of between 10% and 30%, ethylene/alkyl methacrylate copolymer having an alkyl methacrylate content of between 10% and 30%, ethylene/acrylic acid copolymer having an acrylic acid content of between 10% and 30%, ethylene/methacrylic acid copolymer having a methacrylic acid content of between 10% and 30%, and ionomer; including a film comprising a PVC intermediate layer positioned between two layers of polyolefin, such as PE, and/or ethylene copolymer such as EVA (Abstract; Col. 2-4.) Wofford et al teach that plasticizers such as epoxized vegetable oil, dialkyl adipate, and dialkyl phthalate may be incorporated into the PVC with examples including approximately 13wt% dioctyl adipate and approximately 2wt% epoxidized soybean oil (Col. 3, lines 1-19; reads upon broadly claimed plasticizers and the like.) Wofford et al further teach that the films can be formed by coextrusion including tubular coextrusion, to produce shrinkable and non-shrinkable films wherein shrinkable films can be

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formed by orienting or stretching the films, to thicknesses between 0.1 and 10 mils, and layer thicknesses as in the examples (Col. 4, lines 43-66.) Wofford et al further teach that the film may include various other materials and additives that read upon the claimed "antifogging agent" (Col. 3, lines 63-66.)

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- 6. Claims 1-7, 9, 12, 14, and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Parker et al (USPN 5,593,786.) Parker et al teach a polyvinyl chloride adhesive interlayer film comprising a three layer structure including a plasticized PVC core, and polymeric adhesive layers on one or both major surfaces; wherein the total plasticizer concentration is between about 35 and about 45 phr, with suitable plasticizers including linear or branched, or aromatic aliphatic diesters, triesters or tetraesters (Abstract; Col. 4, line 66-Col. 5, line 19.) Parker et al teach that the adhesive layers are formed as thin films with a thickness of preferably about 0.01 to 0.5 mils; on the PVC core or support having a thickness of between about 28 to 35 mils (Col. 3, lines 49-52; Col. 7, lines 23-27.) The adhesive layers are formed from polymeric materials including poly(ethylene-co-vinyl-acetate-co-acrylic acid) (*reads upon PE and EVA*) and may be coextruded with the support layer to produce the multilayer interlayer structure (Col. 6, lines 12-33; Col. 8, line 5-15.)
- 7. Claims 1-7 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Sumi et al (USPN 4,424,834.) Sumi et al teach an elastic article of a coextruded, laminated construction of at least two layers, comprising (a) a layer of a soft polyvinyl chloride combining polyvinyl chloride with a plasticizer and (b) a layer of at least one thermoplastic elastomers wherein the layer of soft polyvinyl chloride incorporates 30 to 220 parts by weight of a plasticizer per 100 parts by weight of polyvinyl chloride (Abstract; Col. 3, lines 60-66.) Sumi et al teach that the

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plasticizer may be a polyester type plasticizer obtained by the reaction of dibasic acids with glycols (Col. 5, lines 5-7.) Sumi et al also teach a three layer structure comprising an intermediate layer of soft PVC protected by outer thermoplastic elastomer layers; with the proportion of the wall thickness of the soft PVC layer to the total wall thickness preferably from 10% to 99.5%; formed by coextrusion and molded by blow molding as to form a tube (Abstract; Col. 6, line 44-Col. 7, line 2; Claim 14.)

- 8. Claims 1, 3-7 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Dehennau et al (USPN 4,774,146.) Dehennau et al teach a flexible thermoplastic structure with multiple coextruded polymeric layers comprising a vinylidene chloride copolymer layer (C) bonded to a plasticized vinyl chloride polymer layer (A), via polymeric adhesive layer(s) B comprising EVA; wherein the plasticizer is may be monomeric or polymeric plasticizers, such as polyesters, in a content of preferably at least 40 parts by weight of plasticizer per 100 parts by weight of vinyl chloride polymer (Abstract; Col. 3, line 54-Col. 4, line 2.) Dehennau et al teach that the film may comprise a structure ABC or ABCBA or ABCDE wherein an additional layer E, such as a polyolefin, an EVA copolymer, a polyester or polyamide, is bonded to the layer C via adhesive D (Col. 2, lines 20-39.) Dehennau et al teach that the films can be formed by coextrusion with the thickness of the layers as recited in Col. 4, lines 37-53 (Col. 4.)
- 9. Claims 1, 3-5, 7, and 15-17 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Goss et al (USPN 7,297,738; also printed as WO03/009339.) Goss et al teach plasticized polyvinyl chloride and the production of a range of goods from the plasticized PVC including highly flexible materials, particularly useful in the production of medical materials such as blood bags and tubing; wherein the plasticized PVC includes 20 to 100 parts by weight

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of esters of cyclohexane polycarboxylic acids which may be used together with other plasticizers, including polymeric plasticizers; per 100 parts by weight of PVC; or a plastisol comprising 40 to 200 parts by weight of the plasticizer per 100 parts of PVC (Abstract; Col. 3, lines 30-56; Col. 4, lines 4-Col. 5, line 49.) Goss et al further teach a multilayer article in which at least two adjacent layers comprise plasticized polyvinyl chloride, and the incorporation of the esters of cyclohexane polycarboxylic acids incorporated into one layer reduces the migration of the plasticizer from one layer to the other (Col. 9, lines 17.) Goss et al further teach that antifogging agents may be incorporated (Col. 15-Col. 16, line 1.)

10. Claims 1-4, 7, 9, 12, and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by JP64-51939A (JP'939.) JP'939 teaches a "soft laminate having excellent oxygen and steam barrier properties, no interlayer exfoliation, softness, excellent moldability and transparency by sequentially laminating a gas barrier layer, a softening material, an adhesive material and a sheet material respectively made of specific resins in this order from an inner layer" (Abstract.) JP'939 teach a coextruded structure comprising a D/C/A/C/B structure wherein (B) is a plasticized vinyl chloride resin containing an anti-fogging agent as a softening material, (C) is an acid modified ethylene resin, and (D) is an ethylene resin such as polyethylene or ethylene-vinyl acetate, containing an antifogging agent; wherein the anti-fogging agent employs glycerin fatty acid ester (Abstract.) JP'939 further teaches that the softened resin B employs low polymer and high polymer plasticizers (Abstract.)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique R. Jackson whose telephone number is 571-272-1508. The examiner can normally be reached on Mondays-Thursdays, 10:00AM-5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on 571-272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Monique R Jackson/ Primary Examiner, Art Unit 1794 September 12, 2008